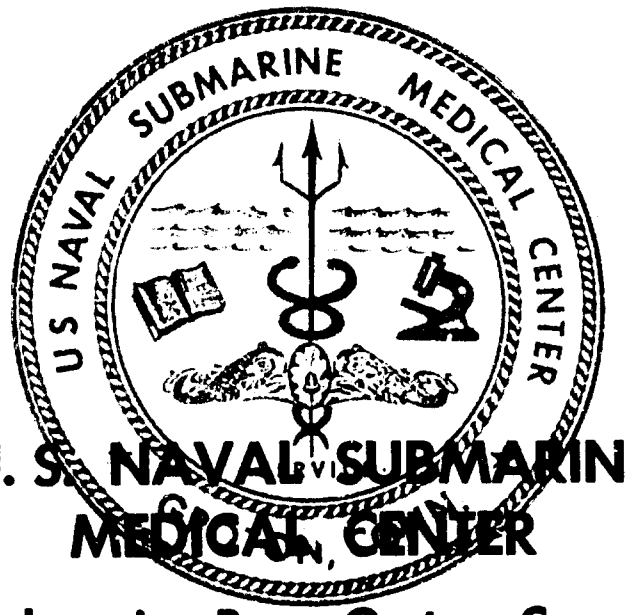

U. S. NAVAL SUBMARINE MEDICAL CENTER

Submarine Base, Groton, Conn.

REPORT NUMBER 565

SHORT TERM CLINICAL EVALUATION OF A CLAY CONTAINING DENTIFRICE

by

CDR William R. Shiller, DC, USN

Bureau of Medicine and Surgery, Navy Department
Research Work Unit MR005.19-6056A.01

Released by:

Gerald J. Duffner, CAPT MC USN
COMMANDING OFFICER
Naval Submarine Medical Center

12 February 1969

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SUBMARINE MEDICAL RESEARCH LABORATORY

NAVAL SUBMARINE MEDICAL CENTER REPORT NO. 565

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SUMMARY PAGE

THE PROBLEM

Gingivitis in military personnel is of constant concern to the Navy Dental Corps both as an immediate problem and as a precursor to degenerative periodontal disease. The causes of gingivitis are almost universally ascribed to the effect of toxic products of the bacterial plaque. An absorbing clay dentifrice compound has been developed which appeared promising in laboratory and animal tests. A clinical evaluation was required to ascertain its practical effectiveness in a military population.

FINDINGS

No significant benefit in gingivitis reduction was noted from the test dentifrice. An appreciable degree of aversion to the taste and to lack of cleaning ability was noted.

APPLICATIONS

The usefulness of this dentifrice has not been demonstrated. The negative subject acceptance might be the reason for the negative results. Further study would be necessary to control for the acceptance factor and evaluate the basic effectiveness.

ADMINISTRATIVE INFORMATION

This investigation was conducted as a part of Bureau of Medicine and Surgery Research Work Unit MR005.19-6056A—Clinical Evaluation of a Clay Containing Dentifrice. This report has been designated as Submarine Medical Research Laboratory Report No. 565. It is report No. 1 on this Work Unit, and was approved for publication as of 12 February 1969.

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ABSTRACT

The causes of gingivitis are almost universally ascribed to the effects of toxic products of the bacterial plaque. One form of control of the disease could therefore include the effective removal of these toxins. A highly absorbing clay dentifrice compound has been developed which appeared promising in laboratory and animal tests.

A short term clinical trial was conducted on 433 Submarine School student volunteers. The subjects were assigned at random to one of three groups: the test group, the positive control (placebo), and the negative control group. The gingival status of each subject was evaluated by standard means before the study and again after ten weeks.

No significant benefits were observed from the agent under study. An appreciable degree of aversion to the taste and to the lack of cleaning ability was noted. It is possible that this lack of subject acceptance may have in large part accounted for the negative results.

SHORT TERM CLINICAL EVALUATION OF A CLAY CONTAINING DENTIFRICE

INTRODUCTION

The promising aspects of a recently developed clay-containing dentifrice[1] has prompted the Navy Dental Corps to investigate its applications in a military population.

The active ingredient of the test dentifrice* is a clay which has extremely high adsorptive qualities. It is postulated that its beneficial action is derived from this absorption of bacterial toxins thus interfering with the action of these toxins on the gingiva. The most significant laboratory work concerning the effectiveness of this material demonstrated the inactivation of periodontal plaque to cause abscesses when injected into the peritoneal cavities of mice. Animal studies have indicated a marked reduction in the periodontal indices of disease prone hamsters treated with this material as compared with placebo treated controls.[1]

The postulated clinical effect of this dentifrice should be both a prevention of gingival inflammation and a resolution of any inflammation present at application.

A two-stage clinical study was therefore proposed and the Atlantic submarine force was selected as a desirable test population. This report covers the results of Stage I of the study.

MATERIALS AND METHODS

The clinical trial was of ten weeks duration and was designed to evaluate the therapeutic aspects of the agent. The test subjects were drawn from a well defined population composed of Submarine School candidates at the Naval Submarine Base New London, Groton, Connecticut.[2] The subjects were selected on the basis of enumerated criteria; they were randomly assigned to test and control groups; and the treatments and evaluations were performed in a double-blind manner

A. **Subjects:** Definite types of subjects were selected from the parent population: those having some degree of gingivitis present (periodontal index score .2 or more). The subjects were otherwise completely unselected.

B. **Composition of groups:** Upon being selected for the study each subject was assigned at random (random numbers) to one of three groups: The test group (dentifrice with active ingredient), the positive control group (placebo dentifrice but handled identically to the test group), and the negative control group (nothing done to the subjects except examination). These allocations were made by the Dental Branch Chief Petty Officer. The examining officer had no knowledge of these assignments.

The groups were numbered A, B and C. Group C consisted of negative control subjects and were necessarily known as such by the Dental Branch Chief Petty Officer. The real character of Groups A and B were not known to anyone in the Dental Branch. The test and the placebo dentifrice codes were in the custody of the Squibb Institute for Medical Research.

C. **Composition of dentifrice:** The test dentifrice contained a highly absorbing clay compound plus other ingredients. The placebo dentifrice was similar to the test material but did not contain the clay compound. The exact formulations are on file with the Federal Drug Administration and at the Submarine Medical Research Laboratory.

D. **Treatment procedure:** The subjects in the test group and the positive control group were given a ten weeks supply of the coded dentifrice. The only instructions given were as follows:

"You have agreed to be a subject in a Navy approved research project. The dentifrice provided you contains ingredients which should improve your oral health. While you are in Submarine School, use this dentifrice instead of that which you usually use. For maximum benefit, you should brush your teeth with this dentifrice after each meal and

*Product of E. R. Squibb & Sons.

before going to bed each night. If you run out of dentifrice, please return to the Dental Research Lab, Building No. 148, for an additional supply. Commander Shiller will reexamine you during your last week of school. Please DO NOT brush your teeth just before coming for the examination. Thank you for your cooperation."

E. **Clinical evaluation of the agent's effectiveness:**

1. **Method of disease assessment:** The variable measured was the degree of gingivitis expressed as a score. The measurement method was a modification of the Periodontal Index as described by Russell.[3] The short term nature of this study would not be expected to allow changes in periodontal pocket characteristics. For this reason, the modification mentioned consisted of the elimination of pocket assessment from the index. In other words, inflammation was scored as follows:

> The gingiva around each tooth was assessed. A score of 0 was given when there was no evidence of inflammation; a score of 1 was given when inflammation was present but did not completely encircle the tooth; and a score of 2 was given when inflammation completely encircled a tooth.

The scores for each tooth were recorded on a record sheet for each subject. They were summed and divided by the total number of teeth present. This represented the modified periodontal index.

2. **Other assessments:** In order to test the correlates of the gingivitis variable, the dental plaque was evaluated as described by Greene and Vermillion[4] and a questionnaire was administered at the end of the study period (see Appendix I).

3. **Times of clinical assessment:** The first examination was made when the subject reported to the Submarine School, New London. The second examination was performed during the last week of Submarine School (10 weeks after the first examination). Conditions were identical to those pertaining in the first examination.

At the end of the test period the dentifrice code was broken and it was found that group A had received the dentifrice containing the active ingredient and group B received the placebo dentifrice.

RESULTS

The gingivitis changes are given in Table I. It is apparent that no remarkable differences in the gingivitis reduction occurred between groups. All groups exhibited about a uniform reduction. Similar results are seen in the case of the plaque indices (Table II). None of the mean values of Table I or Table II show significant differences between groups. Values given are means plus or minus one standard error of the mean.

In Tables III through VIII the responses to a questionnaire are tabulated. It is noted that some subjects were not given the questionnaire. The distribution of the responses show no significant differences between groups. It should be noted that about one-half of the dentifrice subjects did not feel that the dentifrice did a good cleaning job and a vast majority would not choose to continue using the dentifrice. In the same vein, about one-third of the subjects used the supplied dentifrice each time they brushed during the test period.

Tables IX, X, and XI contain data concerning the relationship of the test variable (gingivitis reduction) and acceptance factors. Even though some differences are noted in the mean gingivitis reduction, no distinctive pattern emerges and none of the differences are statistically significant. Unfortunately, the numbers involved in Table XI were not sufficient to get a valid relationship evaluation. This question was added near the end of the study.

Tables XII, XIII, XIV, and XV illustrate the relationship between responses. Again, no real differences are noted between groups. It is perhaps noteworthy that taste and cleansing effectiveness related strongly positively with the subject's acceptance.

Table 1

Gingivitis changes during the study

Group	N	Initial Score	Final Score	Change (Reduction)
A	148	0.425 ± 0.019	0.323 ± 0.021	0.102 ± 0.018
B	139	0.416 ± 0.020	0.332 ± 0.021	0.083 ± 0.020
C	146	0.429 ± 0.019	0.323 ± 0.020	0.106 ± 0.020

Table 2

Plaque changes during the study

Group	N	Initial Score	Final Score	Change (Reduction)
A	148	1.129 ± 0.046	0.795 ± 0.046	0.33 ± 0.044
B	139	1.065 ± 0.042	0.832 ± 0.046	0.233 ± 0.053
C	146	1.072 ± 0.046	0.808 ± 0.045	0.264 ± 0.049

Table 3

Frequency of toothbrushing

Group	N	Seldom	Usually once each day	At least once each day	Twice a day	Three or more times a day
A	109	3	26	46	32	2
B	101	2	22	41	35	1
C	109	6	21	38	38	6

Table 4

Bowel Movement changes during the study

Group	N	More frequent	Less frequent	No change
A	109	5	0	104
B	101	1	3	97
C	109	1	4	104

Table 5

Assessment of the dentifrice taste

Group	N	Tasted good	Did not taste bad	Tasted bad
A	109	20	74	15
B	101	19	65	17

Table 6

Subjective assessment of effectiveness

Group	N	Did a good job	Did not do a good job
A	109	54 (50%)	55
B	101	61 (60%)	40

Table 7

Would you continue using the dentifrice?

Group	N	Yes	No
A	109	33	76
B	101	32	69

Table 8

Did you use the dentifrice each time you brushed?

Group	N	Yes	No
A	62	46 (74%)	16
B	43	37 (86%)	6

Table 9

Gingivitis reduction - toothbrushing frequency relationship

		Brushing Frequency		
Group	N	Brush less than once a day	Brush at least once a day	Brush 2 or more times a day
A	109	0.097* ± 0.038 (N = 29)	0.124 ± 0.035 (N = 46)	0.029 ± 0.035 (N = 34)
B	101	0.029 ± 0.035 (N = 24)	0.054 ± 0.033 (N = 41)	0.097 ± 0.035 (N = 36)
C	109	0.096 ± 0.057 (N = 27)	0.103 ± 0.035 (N = 38)	0.089 ± 0.029 (N = 44)

*Mean gingivitis reduction

Table 10

Relationship between gingivitis reductions and subjective effectiveness assessment

Group	Did a good job	Did not do a good job
A	0.085 ± 0.026 (N = 54)	0.089 ± 0.034 (N = 55)
B	0.074 ± 0.024 (N = 61)	0.048 ± 0.035 (N = 40)

Table 11

Relationship between gingivitis reduction and statement of use

Group	Used it	Did not use it
A	0.087 ± 0.031 (N = 46)	0.006 ± 0.054 (N = 16)
B	0.041 ± 0.034 (N = 37)	0.033 ± 0.084 (N = 6)

Table 12

Relationship between taste and indications of future acceptance

Taste response	Group	Intention of future use: Would continue use	Would not continue use
Tasted good	A	12	8
	B	15	4
Did not taste bad	A	21	53
	B	17	48
Tasted bad	A	0	15
	B	0	17

Table 13

Relationship between subjective effectiveness assessment and indications of future acceptance

Effectiveness assessment	Group	Indications of future acceptance: Would continue using it	Would not continue using it
Did a good job	A	33	21
	B	30	31
Did not do a good job	A	0	55
	B	2	38

Table 14

Relationship between subjective effectiveness assessment and taste

Effectiveness assessment	Group	Taste: Tasted good	Did not taste bad	Tasted bad
Did a good job	A	14	37	3
	B	15	17	0
Did not do a good job	A	6	37	12
	B	4	48	17

Table 15

Relationship between subjective effectiveness assessment and statement of use

Effectiveness assessment	Group	Used it	Did not use it
Did a good job	A	25	8
	B	25	1
Did not do a good job	A	21	8
	B	12	5

DISCUSSION AND CONCLUSIONS

The first and foremost conclusion must be the apparently similar behavior of all three groups. The active agent evidently did not exert its expected influence on the gingival health of this group either from a lack of effectiveness or from some unknown factor in the test population.

One factor worthy of mention in this test concerns an oral hygiene lecture which is now given to all submarine students after they are "classed up." Perhaps this could account for the reduction in the gingivitis and in the plaque during the school period.

The taste and cleansing ability of the dentifrice obviously leaves a lot to be desired. It is highly possible that these two factors could have influenced the outcome. Unfortunately, the study did not control for the use factor. Perhaps a short term, acute study using some manner of controlled applications would be of value in exploring the basic effectiveness of the active ingredient.

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Appendix I

NAME_____

1. How often do you brush your teeth?
   a. Seldom
   b. Usually once each day
   c. At least once each day
   d. Twice each day
   e. Three or more times each day

2. Have there been any changes in your bowel movements since entering Sub School?
   a. Yes, more frequent
   b. Yes, less frequent
   c. No change

3. Were you given the special toothpaste? a. Yes b. No

   If answer is NO, do not answer remaining questions. If answer is YES, complete remaining questions.

4. How would you classify the taste of the toothpaste?
   a. Tasted good
   b. Did not taste bad
   c. Tasted bad

5. How do you think the toothpaste cleaned your teeth?
   a. Did a good job
   b. Did not do a good job

6. Would you continue using the toothpaste?
   a. Yes
   b. No

7. Did you use the special toothpaste each time you brushed?
   a. Yes
   b. No

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13. ABSTRACT

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